Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
New Orleans, LA

Appeal of:	**ROBERT ODELL MD PHD MEDICAL ENTERPRISES**	OMHA Appeal No.:	**3-4473095430**
Beneficiary:	**[Multiple- See Attachment A]**	Medicare Part:	B
Medicare No.:	**[Multiple- See Attachment A]**	Before:	**John C. Rabon** Administrative Law Judge

DECISION

After carefully considering the evidence presented in the record, I enter a **FULLY FAVORABLE** decision for Robert Odell MD Ph D Medical Enterprises ("Appellant" or "Dr. Odell"). Attachment A submitted with this decision specifies the Beneficiaries, the claims at issue, and the dates of service involved in this appeal. Medicare is responsible for payment for the covered services.

PROCEDURALHISTORY

The Appellant seeks reimbursement for multiple physician services denoted by CPT code 64450[1], injection of an anesthetic agent (nerve block) for therapeutic procedures on somatic nerves. This medical treatment was administered to thirty-three different Beneficiaries during the dates of service May 1, 2013 through July 26, 2013 ("Dates of Service"). (See Appendix A). The claims were initially allowed. They were subsequently audited by a Recovery Audit Contractor ("RAC"), Health Data Insights. The RAC determined that the Appellant received an overpayment. The lower levels, the Medicare Administrative Contractor ("MAC"), and the Qualified Independent Contractor ("QIC"), denied the claims. The QIC found the Appellant liable for the overpayment.

1 The Centers for Medicare and Medicaid Services mandates the use of Current Procedural Terminology ("CPT") codes. In the Omnibus Budget Reconciliation Act in 1987, CMS mandates the use of CPT codes for reporting outpatient hospital surgical procedures. By the Health Insurance Portability and Accountability Act ("HIPAA") of 1996, the Department of Health and Human Services designated CPT and Healthcare Common Procedure Coding System ("HCPCS") as the national standards for electronic transaction of healthcare information. CMS developed the HCPCS to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). The CPT/HCPCS code 64450 denotes "injection, anesthetic agent; other peripheral nerve or branch."

The Appellant submitted a written request for an Administrative Law Judge ("ALJ") hearing to the Office of Medicare Hearings and Appeals ("OMHA"). The amount in controversy meets the jurisdictional requirement for an ALJ hearing.

A telephone conference hearing was held on September 9, 2020. The Appellant, Dr. Odell, appeared and was represented by George Brew, Esq. James Hedgcock, DC, Ph. D, and Ron Davis appeared as witnesses for the Appellant. Dr. Odell, Dr. Hedgcock, and Mr. Davis were sworn. Dr. Odell and Mr. Davis testified. There was no appearance made on behalf of The Centers for Medicare Services' ("CMS") Contractors.

All exhibits previously filed into the record were admitted without objection. This appeal involves 108 claims from 33 beneficiaries. Due to the number of appeals involved, there are voluminous records that were forwarded from the QIC. However, these records were not ideally organized and it was difficult to locate pertinent records. I note that neither the QIC nor the MAC, denied these claims based on a lack of documentation.

"New evidence" was submitted by the Appellant. This consisted of records that were organized by Beneficiary. Pursuant to 42 C.F.R. § 405.1018(c), "any evidence submitted…prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evideuce was not previously submitted to the QIC, or a prior decision-maker." If the ALJ receives new evidence, he must examine the new evidence submitted with the request for hearing as specified in 42 § 405.1018 (a)-(c) to determine whether there is good cause for submitting the evidence for the first time at the ALJ level. On examination of the newly filed evidence, and based on the Appellant's counsel's representation that the evidence was previously submitted, I find good cause to admit the new evidence. These documents were added to the record as files 13-46. A prehearing brief was added as files 10 and 11. A notice of hearing was added as file 12, and the response to the notice of hearing was added as file 9.

ISSUE(S)

1. Whether the nerve block injections ("Nerve Blocks") that were provided to the 33 Beneficiaries that are listed on the notice of hearing and in the QIC decision by the Appellant during the Dates of Service are covered under Part B of the Medicare program.

2. If the services are not covered under §1862(a)(1)(A), whether payment may be made under the limitation on liability provisions of §1879 of the Act.

3. Whether the Appellant was overpaid?

4. If it is determined an overpayment exists, whether the Appellant was without fault, as defined in section 1870 of the Act, warranting a waiver of the overpayment?

APPLICABLE LAW AND POLICY

I. Statutes and Regulations

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services ("CMS"), and Title 42 of the Code of Federal Regulations contains implementing regulations. The Supplementary Medical Insurance program, Part B of Title XVIII of the Act, provides coverage for a variety of medical services and supplies furnished by

physicians, or by others, in connection with physician's services, for outpatient hospital services, and for a number of other specific health-related items and services. *See* § 1832 of the Act; *see also* 42 C.F.R. § 410.10.

Section 1862(a)(1)(A) of the Act provides that notwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. *See* 42 C.F.R. § 411.15(k).

Section 1833(e) provides that no payment shall be made to any provider of services unless the record contains information necessary to determine the amounts due to such provider. *Id.* at § 424.5(a)(6). When items or services are not covered because they are found to be not medically reasonable or necessary, a party's lack of knowledge of non-coverage may limit their liability. Act §1879; §§411.400-408; *Medicare Claims Processing Manual (MCPM),* pub. 100-04, ch. 30; CMS Ruling 95-1.

II. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See* 42 C.F.R. §405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued manuals and local coverage determinations ("LCDs") as policy guidance, and to establish criteria for coverage of selected types of medical items and services. ALJ's are not bound by the manuals or the LCD's, but they are to give substantial deference to these policies when applicable. 42 C.F.R. § 405.1062. If an ALJ does not follow a policy in a particular case, the ALJ must explain why the policy was not followed. (*Id.*).

National Coverage Determination (NCD) 310.1, which pertains to clinical trials, applies to this case.

> Effective for items and services furnished on or after July 09, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and uecessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply. NCD 310.1.
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> Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:
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> - The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
> - The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
> - Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group. NCD 310.1 (A).

NCD 310.1 (A). The NCD further provides:

> The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:
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> 1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
> 2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
> 3. The trial does not unjustifiably duplicate existing studies;
> 4. The trial design is appropriate to answer the research question being asked in the trial;
> 5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
> 6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
> 7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

NCD 310.1 (A). There are three ways for a clinical trial to be considered a qualifying clinical trial for purposes of Medicare payment for routine costs relating to a trial. *Id.*

> Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries…
>
> Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

NCD 310.1 (B). With regard to the items and services considered routine costs of a clinical trial, the NCD provides:

> Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:
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> - The investigational item or service, itself, unless otherwise covered outside of the clinical trial;
> - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

- Items and services customarily provided by the research sponsors tree of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service - in particular, for the diagnosis or treatment of complications.

NCD 310.1 (A).

Local Coverage Determination L28240 provides that nerve blocks can be effective procedures when used therapeutically to relieve chronic pain, intraoperatively to prevent pain of the procedure, or diagnostically to ascertain the cause of pain. Nerve blocks are useful in the treatment of a variety of circulatory and neuropathic syndromes. During its effective dates, June 8, 2008 through September 15, 2011, LCD L28240 governed the use of nerve blocks billed under CPT code 64450. Local Coverage Determination L28240; Indications and Limitations of Coverage and/or Medical Necessity Nerve Blocks (LCD L28240)(Retired Sept. 2011).

Generally, Local Coverage Determinations ("LCDs") are retired due to lack of evidence of current problems, or because the material is addressed by a National Coverage Determination, a coverage provision in a Centers for Medicare & Medicaid Services interpretative manual, or an article. Most LCDs are not retired because they are incorrect. Even if an LCD is retired, the guidance provided in the retired LCD may be helpful in assessing medical necessity. Noridian Healthcare Solutions, LCD Retirement Clarification, Noridian, January 14, 2020.

FINDINGS OF FACT AND ANALYSIS

I. *Findings of Fact*

The claims at issue arise from the Appellant's medical treatment of 33 Beneficiaries. Each of the Beneficiaries presented to the Appellant for treatment of pain of varying degrees and types (numbness, tingling, and/or pain, for example) in their lower extremity(s). Each was diagnosed with an unspecified circulatory system disorder, ischemia, denoted by International Classification ("ICD") code 459.9.[2] During the period May 1, 2013 through July 26, 2013, the Appellant treated the Beneficiaries' ischemia with at least one and up to eight Nerve Blocks and

2 ICD codes are the international diagnostic classification standard for reporting diseases, disorders, injuries, and health conditions for all clinical and research purposes.

denoted as CPT code 64450.[3] (Hearing Audio, September 9, 2020, File 2- the QIC Reconsideration Decision, and Files 8, 13-46).

II. Analysis

At issue is whether the Nerve Blocks administered by the Appellant to the Beneficiaries on the Dates of service meet Medicare criteria. The QIC denied coverage based on its finding that the nerve blocks were investigational. The medical treatment was not conducted within a qualifying clinical trial; therefore, Medicare coverage for the treatment as routine costs of a clinical trial was not available.

The Appellant asserts that the medical treatment rendered was not experimental. Instead, before and during the Dates of Service, nerve blocks were an established method of eliminating and/or relieving painful conditions resulting from ischemic disorders. Dr. Odell testified that he had been administering nerve blocks since 2008, if not before, to reduce or illuminate lower extremity pain caused by ischemia successfully. (Hearing Recording, September 9, 2020).

In support of its position, the Appellant cites LCD L28240. LCD L28240 was in effect from 2008 through 2012. LCD 28240 states, "[nerve] [b]locks are useful in a variety of circulatory and neuropathic syndromes." This LCD's guidance supports that at all relevant times, Medicare criteria deemed the medical treatment at issue to be an established and effective method of treatment of the Beneficiaries' conditions. (Appellant's position paper submitted to the ALJ, File 10, 11 and Hearing Audio).

Additionally, and alternatively, the Appellant asserts that the medical treatment at issue was administered in the context of a qualified clinical trial. The clinical trial was registered with the National Institute of Health registry in November 2013, but the registration was retroactively extended back to March 2012. The registration is verified at www.clinicaltrials.gov, registration number NCT 01979367. The trial is titled "The Study of Neurological Ischemia Lower Extremity Pain and Swelling" ("Clinical Trial"). (File 8, pp. 112-114; 115-123). The Appellant was a principal investigator in the Clinical Trial. (*Id.* at 114). The claims at issue are routine costs associated with the Clinical Trial.

After conducting a *de novo* review, I find that the preponderance of the evidence supports that Medicare criteria for the Nerve Blocks administered to the 33 Beneficiaries are met in this case.

1. These services are covered and payable under Medicare Part B because they were medically reasonable and necessary.

Here, the medical records, together with guidance from LCD L28240 and NCD 310.1, support that the medical treatment at issue, Nerve Blocks, meet Medicare criteria.

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3 The Centers for Medicare and Medicaid Services ("CMS") mandates the use of Current Procedural Terminology ("CPT") codes. As part of the Omnibus Budget Reconciliation Act in 1987, CMS mandated the use of CPT for reporting outpatient hospital surgical procedures. As part of the Health Insurance Portability and Accountability Act ("HIPAA") of 1996, the Department of Health and Human Services designated CPT and Healthcare Common Procedure Coding System ("HCPCS") as the national standards for electronic transaction of healthcare information. CMS developed the HCPCS to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). The CPT/HCPCS code 64450 denotes "injection, anesthetic agent; other peripheral nerve or branch."

Local Coverage Determinations are decisions that are published by Medicare Administrative Contractors ("MACs") in accordance with Section 1862(a)(1)(a) of the Act. The term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service meets the "reasonable and necessary" criteria established by section 1862(a)(1)(A) of the Act. CMS: Local Coverage Determinations, https://www.cms.gov/Medicare/Coverage/DeterminationProcess/LCDs.

LCD L28240 provides that nerve blocks are medically necessary for the therapeutic treatment of various circulatory syndromes. This LCD references explicitly and includes the type of treatment, nerve blocks, CPT code 64450, that the Appellant rendered to the Beneficiaries for relief of lower extremity pain caused by ischemia. This LCD is on point in this case.

LCD L28240 was retired in September 2011. Noridian Healthcare Solutions (the MAC that previously reviewed and denied the Appellant's claims) has published an advisory concerning the implications of the retirement of a LCD. The reason that most LCDs are retired is *not* because they are incorrect. More likely, they are retired due to lack of evidence of current problems with the subject of the LCD, or a National Coverage Determination, or another CMS publication was published which addresses the issue. "The guidance in the retired LCD may be helpful in assessing medical necessity." *See* Noridian Healthcare Solutions, LCD Retirement Clarification, Noridian, January 14, 2020.

In this case, the MAC did not suggest that since the retirement of LCD L28240, other rules or regulations have "retracted" LCD L28240's prior declaration that nerve blocks are medically necessary for the therapeutic treatment of circulatory syndromes.[4] Given the circumstances, if such a rule or regulation existed, it is expected that the MAC would have cited it. Neither the QIC, nor the MAC, has cited to any indication that there was a change in the medical consensus opinion about the appropriateness of this treatment.

Because the record is without any basis for the assertion that LCD 28240 should uot be relied on for claims arising during the Dates of Service, I find that the guidance provided by LCD 28240 is helpful in my assessment of the medical necessity of the treatment made subject of the claims before me. I have reviewed the records for each Beneficiary. I note that each of these Beneficiaries were diagnosed with circulatory or peripheral pain. (Files 8, 13-46). I also note that these records contained a description of the procedure (*Id.*). For those Beneficiaries that received more than three injections during a sixty day period, these records also demonstrate the necessity for the additional injections (*Id.*). I find that there is sufficient evidence to establish that this procedure was medically reasonable and necessary for each claim.

Based on the guidance of LCD 28240, together with the medical records before me, I find that the Nerve Blocks administered by the Appellant to the Beneficiaries were not experimental because the LCD indicated that this procedure was covered and payable through the LCD retirement date of September 15, 2011. There is no evidence to suggest that there is a been a change in the applicable medical standards since the retirement of the LCD. I further find that the Nerve Blocks meet the reasonable and necessary criteria established by section 1862(a)(1)(A) of the Act for the treatment of the Beneficiaries' conditions. *See* LCD 28240.

4 The decision-makers below did not assert that LCD L28240 did not meet Medicare criteria of being clear and concise or that the LCD restricted or conflicted with NCDs or coverage provisions in interpretive manuals. *See, Medicare Program Integrity Manual (MPIM)* pub. 100-08, ch. 13, § 13. 5 (Effective January, 2013).

2. In the alternative, these services are covered and payable under Medicare Part B because they were routine costs for a duly registered, qualified clinical trial.

Going to the impact of the Clinical Trial on this case. The Clinical Trial was a "qualified" clinical trial, duly registered at www.clinicaltrials.gov, registration number NCT 01979367, as "The Study of Neurological Ischemia Lower Extremity Pain and Swelling." The start date of the Clinical Trial was March 2012. The Clinical Trial's anticipated completion date was March 2018, and the last verification of the Clinical Trial was February 2015. The Dates of Service are encompassed in the time period of the Clinical Trial.

The Appellant was one of five (5) principal investigators of the Clinical Trial. *See* www.clinicaltrials.gov; *see also* NCD 310.1. The inclusion requirements were that the Beneficiary be over the age of 50, have a high probability of five year survival, and that the Beneficiary be able to comprehend and sign informed consent (File 8, p. 116-117).

This study was designed to access the effectiveness of Monochromatic Infrared Photo Energy (MIRE) and Transcutaneous Electrical Nerve Stimulation (TENS) therapies. The study designed called for the usage of nerve block treatment to control pain until such time as the MIRE or TENS therapies replace the need for additional pain control measures (File 8, p. 116-123).

Each of the Beneficiaries involved in this appeal were over the age of 50, and there is no indication to suggest that they did not meet the other criteria of the study. During the Dates of Service, the Appellant treated each of the Beneficiaries' ischemia with Nerve Blocks, denoted by CPT code 64450. This medical treatment was administered in the context of the Clinical Trial. The medical treatment was a routine cost of the Clinical Trial. Medicare covers the routine costs of the medical treatment rendered in the context of the Clinical Trial. *See* NCD 310.1.

Based on the foregoing, I find that the claims at issue are covered by and payable under Medicare Part B. *See* Section 1833(e) of the Act; *see also* 42 C.F.R. § 424.5(a)(6).

III. Limitation on Liability

Because Medicare Part B covers the outpatient therapy services at issue, the issues regarding limitation on liability and overpayment are moot.

CONCLUSIONS OF LAW

I find the services furnished to the Beneficiaries during the Dates of Service were medically reasonable and necessary under 1862(a)(1)(A) of the Act and applicable guidance, and that they are also covered services as routine costs in a clinical trial under NCD 310.1. Therefore, the overpayment assessment is invalid. The claimed services are covered by and payable under Medicare Part B.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE**. I direct the Medicare administrative contractor to process the claim in accordance with this decision.

SO ORDERED

NOV 19 2020

John C. Rabon
Administrative Law Judge